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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/894,356	08/18/1997	TOSHIHIKO ASHIKARI	001560-308	8892

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EXAMINER

IBRAHIM, MEDINA AHMED

ART UNIT PAPER NUMBER

1638

DATE MAILED: 02/22/2002

32

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

08/894,356

Applicant(s)

ASHIKARI ET AL.

Examiner

Medina Ibrahim

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 40/20/01 and 09/19/01.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3, 5-12, 20 and 22-53 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-12, 20 and 22-53 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Art Unit: 1638

### **DETAILED ACTION**

The text of these sections of the Title 35, U.S. Code not included in this action can be found in prior Office actions.

Claims 1-3, 5-12, 20, 22-53 are pending in this application and are under examination.

Applicants' response and the supplemental response of 4/20/01 and 9/20/0, respectively have been considered.

#### ***Written Description***

Claims 1-3, 5-12, 20, 22-45, and 48-53 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants' arguments filed on 04/20/01, to the extend it applies to this rejection, have been fully considered but they are not persuasive. The claims encompass an isolated gene that hybridizes with a consensus region or all of the nucleotide sequence encoding any of SEQ ID NO:1 to 6, under specified ( low to moderate) hybridization conditions, or isolated gene encoding a protein with amino acid sequence with at least 30% or 69% homologous to the disclosed amino acid sequences. The specification discloses isolated nucleotide sequences encoding SEQ ID NO:1-6. The specification does not disclose any physical or chemical characteristics or any other relevant identifying characteristics for genes that hybridize under the claimed hybridization conditions to the disclosed sequences or homologous sequences with at least 30% or 69% to SEQ ID NO:1-6, and a review of literature does not indicate that

Art Unit: 1638

such characteristics would be well known by an skilled artisan. DNA sequences obtainable under the hybridization conditions set forth in claims 5-6 and 28-45 are expected to yield structurally and/or functionally unrelated DNAs which applicants were clearly not in possession at the time the application was filed. Likewise, DNA sequences encoding proteins with as low as 30 or 69% homologous to the disclosed sequences are also expected to be highly variable and unrelated to the claimed sequences. While Applicants are not required to disclose each and every member of the species encompassed by the claim or what is known in the prior art, the law requires that specification provides sufficient written description which would allow a skilled artisan to visualize or recognize the identity of the members of the genus. In this case, the specification does not adequately describe the genus of sequences with as low as 30% homologous to the disclosed sequences or sequences that hybridize under low hybridization conditions to the disclosed sequences. Claims 1-3, 9-12, 25-27, 46-47, and 53 are included in the rejection because the claims recite "gene" which includes non-coding region as well as all regulatory sequences associated with expression, which were not described in the specification. Therefore, given the lack of written description as discussed above, a person skilled in the art would not recognize from the disclosure that Applicant was in possession of the invention as broadly claimed.

See, Written Description Examination Guidelines published in Federal Registry/Vol. 66, No.4/Friday, January 5, 2001/Notices). See, also *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an

Art Unit: 1638

adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

***Claim Rejections - 35 USC 112***

Claims 1-3, 5-12, 20, 22-45, and 48-53 are rejected under 35 U.S.C. 112, first paragraph, because the specification while being enabling for isolated nucleotide sequences encoding an anthocyanin acyltransferase including those encoding SEQ ID NO:1-6 and transgenic plant or plant parts expressing said sequences, does not provide enablement for any isolated gene which hybridizes with the disclosed nucleotide sequences under the specified hybridization conditions or nucleotide sequences encoding a protein having at least 30% or 69% amino acid sequence homology to SEQ ID NO:1-6, and still retaining anthocyanin acyltransferase activity, or methods to acylate or stabilize a pigment in a plant. Applicants' arguments filed on 04/20/01, to the extent it applies to this rejection, have been fully considered but they are not persuasive.

The claims are broadly drawn to isolated gene from source which hybridizes with the disclosed nucleotide sequences under the specified hybridization conditions or nucleotide sequences encoding a protein having at least 30% or 69% amino acid sequence homology to SEQ ID NO:1-6, and still retaining anthocyanin acyltransferase activity. In contrast, the specification discloses isolation of nucleotide sequences encoding an anthocyanin acyltransferase and a method for their use to alter the color of a plant or plant parts. The specification does not enable all the genes of claims 5-8, 28, 42-45, and 48-52 taking into account the *in re Wand* factors (858F.2d

Art Unit: 1638

731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims. The specification does not disclose or provide guidance for isolated genes which hybridizes under the specified hybridization conditions with a consensus region or all of any of the disclosed sequences and still retaining anthocyanin acyltransferase activity. It is unclear as to whether any or all genes which hybridizes, under the specified hybridization conditions, with the consensus region or all of any of the disclosed sequences will encode a protein with anthocyanin acyltransferase activity. The nucleotide sequences obtainable under low conditions may or may not encode a functional enzymes, or may even encode a protein with a different function. Neither the specification nor Applicant's responses provide evidence that this is not the case for the anthocyanin acyltransferase genes. Therefore, it is unpredictable as to whether plants or plant parts expressing genes which hybridizes, under the specified hybridization conditions, with the consensus region or all of any of the disclosed sequences will result the desired phenotype of claims 20, 22-24. Regarding claims 7 and 8, the specification does not disclose or provide guidance for any modifications to the disclosed sequences that resulted homologous sequences with as low as 30% or 69% homology and still retaining the anthocyanin acyltransferase activity. The specification

Art Unit: 1638

does not disclose specific amino acids or residues whose alteration does not affect the protein activity. See, Lazar et al (Molecular and Cellular Biology, March 1988, Vol. 8, No. 3, pp. 1247-1252 (U))) who teach that a mutation of aspartic acid 47 and leucine 48 of a transforming growth factor alpha results in different biological activities (Title). Broun et al (Science, 13 November 1998, Vol. 282, pp. 131-133 (V)) teaches as few as four amino acid substitutions can convert an oleate 12-desaturase to a hydroxylase and as few as six result in conversion of a hydroxylase to a desaturase (Abstract). Accordingly, it is unpredictable whether any modifications to any part of the disclosed amino acid sequence would result in retained enzyme activity and the desired phenotype in transgenic plants expressing . In addition, no transgenic plant or plant part with controlled color as a result of expressing exemplified or non-exemplified sequences has been disclosed. Claims 1-3, 9-12, 25-27, 46-47, and 53 are included in the rejection because the specification does not provide any guidance for the non-coding regions as well as all the regulatory regions of the genes. The prior art does not amend the deficiency.

Regarding Applicant's arguments against undue experimentation, while the determination of hybridizing or homologous sequences are well within the level of one skilled in the art, Applicants have provided no evidence that sequences obtained by structural homology always define functional homology. Sequences obtainable by structural homology may or may not encode functional proteins or may even encode different proteins. Neither the prior nor the instant specification teaches correlation between structural and functional homology of a sequence. In addition, Applicants have provided no guidance as how to eliminate the inoperable embodiments,

Art Unit: 1638

sequences hybridizing under low to moderate hybridization conditions or homologous sequences with as low as 30% homology to the disclosed sequences, that do not retain anthocyanin acyltransferase, which is considered to require undue and excessive experimentations.

Therefore, given the lack of guidance; the unpredictability; the state of the prior art; the nature of the invention; and the limited working as discussed above, one skilled in the art would not be able to practice the claimed invention without undue experimentations.

See Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ 2d 1016 at 1021 and 1027, (Fed. Cir. 1991) at page 1021, where it is taught that a gene is not reduced to practice until the inventor can define it by “its physical or chemical properties” (e.g a DNA sequence) and page 1027, where it is taught that the disclosure of a few gene sequences did not enable claims broadly drawn to any analog thereof.

The rejection is maintained.

***35 USC 112, 2nd paragraph***

Claims 1-3, 5-8, 11, 20, 22-45, and 48-53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-3, 5-9, 20-23, 25, 28-29, 33-36, , 42-53 recite “gene” which implies a DNA sequence that exists in nature and includes coding, non-coding regions, as well as all regulatory sequences associated with expression. This does not appear to be Applicant’s intention, as evidenced by Applicant’s recitation of “isolated”. It is suggested that Applicant amend “gene” to -

Art Unit: 1638

-- polynucleotide---. Dependent claims 10-12, 24, 26-27, 30-32, 37-41 are included in the rejection.

Claims 20, 22-23, and 33-35 "the protein produced" lack antecedence. If the "gene" is to express "a protein" the claim should be recited as such. Also, claims 22- 23 and 34-35 recite incomplete method steps that do not result in "stabilizing" a pigment and "controlling" color of a flower, respectively. Dependent claims 24 is included in the rejection.

What is being claimed in claim 25 is unclear. If Applicant intends to claim " A plant, a progeny or tissues thereof, each whose color has been altered by introducing therein a gene according to claim 1", the claim should be recited as such.

Claim 28 is confusing because SEQ ID NO:1-6 are recited both as amino sequences (line 3) and as nucleotide sequences (lines 4 to 5). Appropriate correction is required. Also, "aryl" after "aromatic" should be changed to ---acyl---Dependent claims 29-41 and 51 are included in the rejection.

In claims 10-12 and 30-32, "host" should be changed to -- host cell--, for clarification.

In claim 35, the metes and bounds of "controlling" are unclear. It is suggested that "controlling" be replaced with ---altering---.

### ***Remarks***

Claims are free of the prior art.

No claim is allowed.

Art Unit: 1638

Papers relating to this application may be submitted to Technology Sector 1 by facsimile transmission. Papers should be faxed to Crystal Mall 1, Art Unit 1638, using fax number (703) 308-4242. All Technology Sector 1 fax machines are available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (703) 306-5822. The Examiner can normally be reached Monday -Tuesday from 8:00 AM to 5:00 PM and Wednesday-Thursday from 9:00AM to 3:00PM

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

February 20, 2002

mai

ELIZABETH F. McELWAIN  
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